

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/29/2010 has been entered.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what the chiral status of the carbon attached to the alpha-amino group is. The reagent II and the intermediate VII both show no chiral indication, meaning that that this is a racemic mixture. The final product of Formula I however, has a chiral indicator in the structural formula (the dashed line to the amino), but not in the canonical name given for that structure, which immediately precedes it. However, there also appear

Art Unit: 1624

in parenthesis the name “cefprozil”, and that drug is chiral at that position. Therefore, there are three indications that the position is not to be chiral (II, VII, and the canonical name) and two indication that it is to be chiral (structural formula and “cefprozil”).

Claims 10-13, 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Note above rejection. As written, the claims appear to use a racemic reagent to obtain a chiral product, but with no resolution step provided. That is certainly not enabled. Fixing the above matter will resolve this rejection as well.

The traverse is unpersuasive. The response does not come to terms with the problem here, which is the discrepancy. Indeed, the remarks do not explicitly state whether they intend the position to be not chiral, as indicated by II, VII, and the canonical name, or whether they intend the product to be chiral, as indicated by the structural formula and “cefprozil”. Instead, applicants simply point to what the specification has, which does not solve the problem, since the same inconsistency is seen in the specification. Instead, applicants say things like “the structure of Formula I is clear from the claim.” The clarity of Formula I – or any of the other formulae for that matter -- is not the issue. The problem is the internal inconstancies between things all of which are clear. That is, the five items, I, II, VII, the canonical name and “cefprozil” are all clear, but are inconsistent with each other.

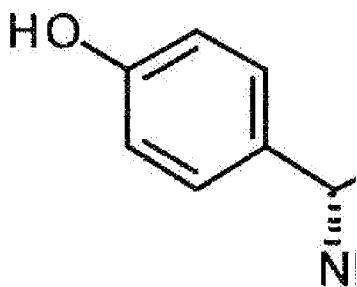
Art Unit: 1624

Applicants need to decide whether they intend chiral or not chiral, and then make the two corrections (to structural formula and “cefprozil”), or make the three corrections chiral (to II, VII, and the canonical name) accordingly.

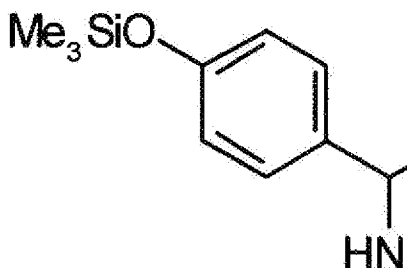
The most recent traverse is unpersuasive. Applicants have not changed Formula II at all, and the fix to VII, while making for formula slightly cleaner, didn't change anything at all.

To reiterate the problem, the discrepancy is at the alpha amino group.

In Formula I:

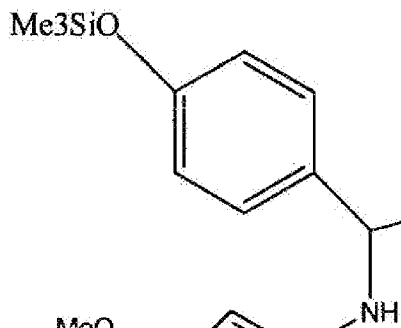


In Formula II:



In Formula III as amended

Art Unit: 1624



Note how Formula I has a chiral indicator for the alpha amino, and the next two, the reactants, do not; there is just a simple line to the N atom. In addition, the canonical name says “2-amino”, not chiral, but the name (‘cefprozil’) is in fact, a chiral compound at that position. Cefprozil is (6R,7R)-7-[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino]-8-oxo-3-(1-propen-1-yl)-5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic Acid; note the (2R).

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

Art Unit: 1624

In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663.

The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/  
Primary Examiner  
Art Unit 1624

4/13/2010